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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/562,648  | 05/02/2006  | Mark A. Rydell       | 109525 002          | 8434             |
| 23526 7590 10/13/2010<br>NORRIS MCLAUGHLIN & MARCUS, P.A.<br>721 ROUTE 202-206<br>P.O. BOX 5933<br>BRIDGEWATER, NJ 08807-5933 |             |                      |                     |                  |
| EXAMINER  |             |                      |                     |                  |
| STEWART, ALVIN J  |             |                      |                     |                  |
| ART UNIT  |             | PAPER NUMBER         |                     |                  |
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/562,648

**Applicant(s)**

RYDELL ET AL.

**Examiner**

Alvin J. Stewart

**Art Unit**

3774

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08/05/10.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7, 19, 20, 22, 24 and 25 is/are pending in the application.
- 4a) Of the above claim(s)    is/are withdrawn from consideration.
- 5) ☐ Claim(s)    is/are allowed.
- 6) ☒ Claim(s) 1-7, 19, 20, 22, 24 and 25 is/are rejected.
- 7) ☐ Claim(s)    is/are objected to.
- 8) ☐ Claim(s)    are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No.   .
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other:

### **DETAILED ACTION**

#### ***Statement under 37 CFR 3.73(b)***

Regarding the 3.73 (b) statement, the Applicant's representative didn't argue or supply a new 3.73(b), therefore, the defective 3.73(b) statement is maintained.

The statement under 37 CFR 3.73(b) is defective. The chain of title from the inventor's to the current assignee is defective. The applicant's representative must enter in column B, column 1 first the inventors to Adv. Bio-Surfaces, then column 2, Adv. Bio-Surfaces to ABS Corp. and col. 3 from ABS Corp. to MEMometal tech. Correction is required. A new 3.73(b) is required.

#### ***Response to Arguments***

Applicant's arguments filed 08/05/10 have been fully considered but they are not persuasive.

Regarding the word: "consisting essentially of monolithic tibiotalar implant", the Applicant's representative still argues that the above phrase clearly signals the exclusion of a structure that contains two or more pieces. As mentioned in the previous Office Action the phrase "consisting essentially of a monolithic tibiotalar implant" equal the word "comprising". See MPEP 2111.03.

The Examiner believes that the specification is still absent of a clear indication in the specification or claims of what the basis and novel characteristics actually are. For example, in page 2, lines 27-30 of the Applicant's specification disclose that the device can be made of a composite or monolith structure. Therefore, there is no criticality or provide a clear indication of

what the basic and novelties of the invention are. Therefore, the Examiner maintains the same interpretation as the previous Office Action. See below.

The Applicant's representative replaced the word "comprising" with the new limitations "consisting essentially of". The phrase "consisting essentially of" claim occupies a middle ground between closed claims that are written in a consisting of format and fully open claims that are drafted in a comprising format. *PPG Industries v. Guardian Industries*, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also *Atlas Powder v. E.I. duPont de Nemours & Co.*, 750 F.2d 951, 137 USPQ 893 (CCPA 1963); *Water Technologies Corp. vs. Calco, Ltd.*, 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purpose of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See e.g. *PPG*, 156 F. 3d at 1355, 48 USPQ2d at 1355.

Regarding the word "monolithic", after a careful examination of the Applicant's arguments the examiner still believes that the prior art can be used as a 102 rejection. The applicant's representative is only claiming a single piece, so the single piece of the prior art is disclosed as element 50, no matter there are other implants that can be used to articulate with element 50. The outer surface (52) of element 50 is capable of being positioned against the natural articulating surface of the patient's tibia and is shaped to allow the tibia to articulate across the first major surface.

Regarding the new limitations regarding the bead, Parks et al clearly discloses the beads at each end of the implant.

The Applicant's representative argues that element 50 of the Parks, et al reference can not be used without the other two elements 40 & 60. As mentioned in the previous Office Action element 50 is a single monolithic piece and is perfectly capable of being used with the natural articulating surface of the patient's tibia.

Regarding the limitations disclosing that the "tibia being allowed to articulate across the first major surface". The Examiner wants to remind the Applicant's representative that those limitations are just functional language and the new entered paragraph "tibia being allowed to articulate across the first major surface" filed on 04/09/10 does not add any structure limitations to the claim. The Examiner has to only find a reference capable of having a tibia being allowed to articulate across the first major surface no matter if the articulation is not 100% efficient as desired by the Applicant. The Examiner just has to find a reference capable of performing the above claimed functional language. The Examiner still believes that the above reference reads on the above claimed functional language.

Regarding claim 22, the Examiner believes that the reference clearly discloses a first mayor surface and a second mayor surface. With respect to the phrase: "substantially free of anchoring portions", the examiner believes that the prior art still reads on the claimed subject matter because the anchoring system of the Parks et al reference is substantially smaller than the anchoring system of other ankle joints, such as anchoring systems that comprise a stem that goes within the intramedullary canal of the femur. Elements 46 and 54(a) are very small anchoring system compare to others such as Patents 7,485,147; 7,314,488, etc...

Regarding the phrase "substantially free of anchoring portions". The Applicant's representative must be careful with the limitations entered in the claims because nowhere in the

specification mentions that the implanted device is "substantially free of anchoring portions....". To be more specific the Examiner was not able to find in the specification the above claimed language. To be more specific col. 5, lines 1-5, clearly discloses that other stabilization methods can be provided to fix the implant to the talus. Therefore, pegs, nails, screws, etc can be used.

The rest of the limitations are functional language.

For the reasons above, the Examiner believes that the rejection is proper. In order to overcome the rejection the Applicant's representative must add more structure limitations that can distinguish the prior art from the patent application.

Regarding claim 25, see element 58 clearly disclosing a bead shaped structure.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-4, 19, 20, 22, and 24-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Parks et al US Patent 7,025,790 B2.

Parks et al discloses an implant (50) having a convex outer surface and a concave inner surface. Wherein the inner surface comprises external structures such as integral bead (see col. 9, lines 61-63 and col. 10, lines 14-18).

Regarding claim 2, the one or more additional external structures can be interpreted as the second bead (58) and element 54(a).

Regarding claim 3, see Fig. 15. All the parts are integral. The term integral was held not to be limited to a fabrication of the parts from a single piece of material, but was inclusive of other means of maintaining the parts fixed together as a single unit. In re Larson et al., 340 F 2d 965, 144 U.S.P.Q. 347 (C.C.P.A. 1965). « integral is sufficiently broad to embrace constructions united by such means as fastening and welding. In re Hotte, 475 F 2d 644, 177 U.S. P.Q. 326 (C.C.P.A. 1973).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parks et al US Patent 7,025,790 B2 in view of Schon US Patent 6,572,620.

Parks et al discloses the invention substantially as claimed. However, Parks et al does not an implant made of polyurethane and a talus-calcaneus implant having a posterior and anterior lips.

Schon disclose a plate (20) capable of being used as a talus-calcaneus implant having an anterior and posterior lips.

Regarding claims 8 & 9, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the Parks et al reference and add another

implant as the plate (20) shown in the Schon reference in order to replace another injured part of the patient's body.

Regarding claims 5-7, It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the polyethylene material of the Parks et al reference with the polyurethane material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J. Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).



If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Isabella can be reached on 571-272-4749. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Alvin J Stewart/  
Primary Examiner, Art Unit 3774

October 11, 2010.